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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,158	09/15/2003	Frederic DeSauvage	11669.123USC1	4053

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EXAMINER
SKELDING, ZACHARY S

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,158	DESAUVAGE ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,49,50 and 57-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,49,50 and 57-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413), Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed October 9, 2007 is acknowledged.

   Claims 1-34, 36-48, 51-56 and 60-68 have been canceled.

   Claim 49 has been amended.

   Claims 35, 49, 50 and 57-59 are pending.

   Claims 35, 49, 50 and 57-59 are under examination as they read on a method for inhibiting the differentiation of Th0 cells into a Th2 subtype comprising administering an effective amount of a TCCR (SEQ ID NO: 1) agonist antibody wherein said antibody binds the species of TCCR that is "human TCCR".

2. The previous rejections of record can be found in the Office Action mailed July 11, 2007.

   This Office Action is in response to Applicant's amendment filed October 9, 2007.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

   > The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 35, 49, 50 and 57-59 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, essentially for the reasons of record as put forth in the Office Action mailed July 11, 2007.

   Applicant argues that the claims have been amended to recite that a fragment of a TCCR agonist antibody comprises two or more TCCR antigen binding sites and that therefore the rejection is overcome.

   Applicant's argument has been considered, but has not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed July 11, 2007.

   Applicant's argument is not found convincing because applicant's amendment about "two or more TCCR antigen binding sites" does not apply to all of the claimed antibodies, rather it only applies to "a fragment of a TCCR (SEQ ID NO: 1) agonist antibody comprising two or more TCCR antigen binding sites."

Thus the following other elements of the rejected claims still encompass antibodies which either are monovalent for TCCR or encompass in their breadth antibodies monovalent for TCCR: "a TCCR (SEQ ID NO: 1) agonist antibody" , "bispecific TCCR (SEO ID NO: 1) agonist antibody" , "a TCCR (SEQ ID NO: 1) agonist diabody", "Fv" and "single-chain antibody", essentially for the reasons of record put forth in the Office Action mailed July 11, 2007.

In addition, given the amendment to claim 49 to recite "a fragment of a TCCR (SEQ ID NO: 1) agonist antibody comprising two or more TCCR antigen binding sites," it is unclear how the skilled artisan would go about making the "single-chain antibody" or the "Fv" fragment of claim 59 that has two or more TCCR antigen binding sites given that according to the instant specification a "single-chain" antibody or an "Fv" comprise the Vh and Vl domains of an antibody and thus are monovalent (see, in particular, the instant specification, pages 28 and 31, 1st paragraphs on both).

In conclusion, the instant specification provides insufficient direction or guidance regarding how to make and use the TCCR agonist antibodies encompassed by the breadth of the instant claims.

Accordingly, undue experimentation would be required to produce the claimed invention commensurate with the scope of the claims from the written disclosure alone. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 35, 49, 50, and 57 stand rejected under 35 U.S.C. 102(b) as anticipated by Baumgartner et al. (U.S. Patent No. 5,792,850, cited by applicant)(see entire document) as evidenced by the instant specification at page 3, 1st paragraph, the paragraph bridging pages 4 and 5 and Figure 1; and page 11, 3rd paragraph, essentially for the reasons of record as put forth in the Office Action mailed July 11, 2007.

Applicant argues that Baumgartner does not anticipate the claimed invention because Baumgartner allegedly does not teach inhibiting or attenuating the differentiation of Th0 cells into a Th2 subtype.

More particularly, applicant confirms that the instant claims, "are directed to administering a TCCR agonist to attenuate or inhibit production of Th2 cells. The claims therefore encompass inhibiting or attenuating humoral immunity with a TCCR agonist."

Furthermore, applicant makes the assertion that "Baumgartner discloses that agonists of Zcytor 1 may be useful for stimulating cell-mediated immunity. Th2 cells, however, are associated with humoral immunity, not cell-mediated immunity. See, for example, Fig. 1 in the specification."

Lastly, applicant argues that since Baumgartner does not teach administering TCCR to inhibit differentiation, and thereby inhibit proliferation, of Th2 cells, Baumgartner does not disclose all the elements of the claims.

Applicant's argument has been considered, but has not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed July 11, 2007.

Applicant appears to be attempting to distinguish the teachings of Baumgartner from the instant claims on the basis of the Baumgartner teachings regarding the mechanism of action of agonists of Zcytor1 and the recited mechanism of action of agonists of TCCR in the instant claims (note that the Zcyto1 and TCCR polypeptides are identical as stated in the previous Office Action mailed July 11, 2007 and will be referred to as "Zcyto1/TCCR" henceforth).

However, as stated in the prior Office Action of July 11, 2007, the instant claims recite "a method of inhibiting or attenuating differentiation of Th0 cells into a Th2 subtype comprising administering..." According to the instant specification, by inhibiting Th2 differentiation the skilled artisan is inherently causing Th1 differentiation, which is useful for treating Th2 mediated disorders characterized by the overproduction of Th2 cytokines such as for treating patients with "exacerbation of infection with infectious diseases" (see paragraph bridging pages 4 and 5 and page 11, 3rd paragraph).

Thus, as evidenced by the instant specification, the instant claims read on a method comprising administering Zcyto1/TCCR agonist antibody to promote the formation of Th1 cells over Th2 cells, thereby stimulating cell mediated immunity (see, in particular, page 3, 1st paragraph, the paragraph bridging pages 4 and 5 and Figure 1). As further evidenced by the instant specification, methods that promote Th1 cells in favor of Th2 cells are useful in treating infectious disease, including, for example, human immunodeficiency virus (see, in particular, the paragraph bridging pages 4 and 5).

Moreover, as stated by applicant in their most recent amendment and remarks, "Baumgartner discloses that agonists of Zcytor 1 may be useful for stimulating cell-mediated immunity," which according to Baumgartner is useful in the treatment of infections involving immunosuppression, including certain viral infections (see Baumgartner, in particular,

column 15, 1st paragraph).

Therefore, the prior art teaches the same method step as claimed in the instant invention directed to the same purpose, i.e., administering a Zcyto1/TCCR agonist antibody to a patient in need of increased cell-mediated immunity, for example, a patient with an infection involving immunosuppression, including certain viral infections.

Put another way, the teachings of the prior art are applicable to the treatment of all patients in need of increased cell-mediated immunity, i.e., increased Th1 activity, and whether this increased Th1 activity is the result of Zyctor 1/TCCR agonist driven induction of Th2 cells or Zyctor 1/TCCR inhibition of Th1 cells, the end result is increased cell-mediated immunity, and the concomitant treatment of infections involving immunosuppression, including certain viral infections.

Applicant's emphasis on the differences of the teaching of Baumgartner versus the teachings of the instant specification with respect to the effect of agonists of Zcyto1/TCCR on humoral versus cell-mediated immunity does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979).

Moreover, applicant has not put forth a convincing argument based on objective evidence and sound scientific reasoning to show that the claim language or limitations of the instant claims result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Accordingly, the instant claims are anticipated by Baumgartner as evidenced by the instant specification at page 3, 1st paragraph, the paragraph bridging pages 4 and 5 and Figure 1, and page 11, 3rd paragraph.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 35, 49, 50 and 57-59 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner et al. (U.S. Patent No. 5,792,850) in view of Queen et al. (US 5,585,089) and Holliger et al. (U.S. Patent No. 5,837,242), essentially for the reasons of record as put forth in the Office Action mailed July 11, 2007.

Applicant argues that "Baumgartner does not teach or suggest administering a TCCR agonist or Zcytor 1 agonist to inhibit or attenuate humoral immunity. The secondary references of Queen and Holliger do not cure the deficiencies of the Baumgartner."

Applicant's argument has been considered, but has not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed July 11, 2007 as well as for the reasons put forth above in Section 6.

Thus, the instant claims stand unpatentable over Baumgartner in view of Queen and Holliger.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 35, 49, 50 and 57-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 20, 23, 24 and 35-39 of copending Application No. 10/088,950, essentially for the reasons of record as put forth in the Office Action mailed July 11, 2007.

    It does not appear that applicant responded to the nonstatutory obviousness-type double patenting rejection put forth in the Office Action mailed July 11, 2007.

    Thus, the instant rejection is maintained for the reasons of record put forth in the Office Action mailed July 11, 2007

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented at this time.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
December 24, 2007

MICHAIL BELYAVSKYI, PH.D.
PRIMARY EXAMINER

12/26/07